

#2

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Rec'd PCT/PTO 11 FEB 2005**

Applicants : Hee-Yong LEE et al.

Group Art Unit : Not Yet Assigned

Appl. No. : 10/512,090

(U.S. National Stage of PCT/KR03/00921)

Examiner : Not Yet Assigned

I.A. Filed : May 9, 2003

For : SUSTAINED RELEASE FORMULATION OF PROTEIN AND  
PREPARATION METHOD THEREOF**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop AMENDMENT  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir :

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification and the International Search Report issued in connection with International Patent Application No. PCT/KR03/00921, of which the present application is the U.S. National Stage Application. A copy of the International Search Report (in English) was enclosed with the papers when entering the National Stage on November 9, 2004. The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the documents cited therein. The following is a list of the documents cited in the above-noted documents:

J. HELLER et al., Biomaterials, Vol. 4, pp. 262-266, October 1983.

Applicants note that this document is cited on page 1 of the specification of the present application;

R. LANGER, Science, Vol. 249, No. 4976, pp. 1527-1533, September 28, 1990. Applicants note that this document is cited on page 1 of the specification of the present application;

H. OKADA et al., Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 12, No. 1, pp. 1-99, 1995. Applicants note that this document is cited on page 1 of the specification of the present application;

T.G. PARK, Biomaterials, Vol. 16, pp. 1123-1130, 1995. Applicants note that this document is cited on page 2 of the specification of the present application;

J.M. ANDERSON, Advanced Drug Delivery Reviews, Vol. 28, pp. 5-24, 1997. Applicants note that this document is cited on page 2 of the specification of the present application;

M.A. TRACY et al., Biomaterials, Vol. 20, pp. 1057-1062, 1999. Applicants note that this document is cited on page 2 of the specification of the present application;

J.P. McGEE et al., Journal of Controlled Release, Vol. 34, pp. 77-86, 1995. Applicants note that this document is cited on page 2 of the specification of the present application;

B. GANDER et al., J. Microencapsulation, Vol. 12, No. 1, pp. 83-97, 1995.

Applicants note that this document is cited on page 2 of the specification of the present application;

P.B. O'DONNELL et al., Advanced Drug Delivery Reviews, Vol. 28, pp. 25-42, 1997. Applicants note that this document is cited on page 2 of the specification of the present application;

U.S. Patent No. 4,818,542 to DeLUCA et al., which issued on April 4, 1989. Applicants note that this document is cited on page 2 of the specification of the present application;

U.S. Patent No. 5,942,253 to GOMBOTZ et al., which issued on August 24, 1999. Applicants note that this document is cited on page 2 of the specification of the present application;

H.K. KIM et al., Biotechnol. Bioeng., Vol. 65, pp. 659-667, 1999.  
Applicants note that this document is cited on page 3 of the specification of the present application;

G. CROTTA et al., J. Microencapsulation, Vol. 15, No. 6, pp. 699-713, 1998. Applicants note that this document is cited on page 3 of the specification of the present application;

U.S. Patent No. 5,804,557 to CLELAND et al., which issued on September 8, 1998. Applicants note that this document is cited on page 3 of the specification of the present application;

J.L. CLELAND et al., Pharmaceutical Research, Vol. 13, No. 10, pp. 1464-1475, 1996. Applicants note that this document is cited on page 3 of the specification of the present application;

J.L. CLELAND et al., Pharmaceutical Research, Vol. 14, No. 4, pp. 420-425, 1997. Applicants note that this document is cited on page 3 of the specification of the present application;

J.-M. PEAN et al., Pharmaceutical Research, Vol. 16, No. 8, pp. 1294-1299, 1999. Applicants note that this document is cited on page 3 of the specification of the present application;

A. SANCHEZ et al., International Journal of Pharmaceutics, Vol. 185, pp. 255-266, 1999. Applicants note that this document is cited on page 3 of the specification of the present application;

E.C. LAVELLE et al., Vaccine, Vol. 17, pp. 512-529, 1999. Applicants note that this document is cited on page 3 of the specification of the present application;

M. IWATA et al., J. Microencapsulation, Vol. 16, No. 1, pp. 49-58, 1999. Applicants note that this document is cited on page 4 of the specification of the present application;

U.S. Patent No. 5,019,400 to GOMBOTZ et al., which issued on May 28, 1991. Applicants note that this document is cited on page 4 of the specification of the present application;

U.S. Patent No. 5,654,010 to JOHNSON et al., which issued on August 5, 1997. Applicants note that this document is cited on page 4 of the specification of the present application;

J.L. CLELAND et al., Current Opinion in Biotechnology, Vol. 12, pp. 212-219, 2001. Applicants note that this document is cited on page 4 of the specification of the present application;

P.S. DANNIES, Molecular and Cellular Endocrinology, Vol. 177, pp. 87-93, 2001. Applicants note that this document is cited on page 9 of the specification of the present application;

M.G. FARQUHAR et al., Endocrinology, Vol. 102, No. 1, pp. 296-311, 1978. Applicants note that this document is cited on page 10 of the specification of the present application;

International Patent Application Publication No. WO 01/28524, which was published on April 26, 2001, together with patent family members U.S. Patent Application Publication No. 2003/0059474 to SCOTT et al., which was published on March 27, 2003 and U.S. Patent No. 6,458,387 to SCOTT et al., which issued on October 1, 2002;

International Patent Application Publication No. WO 99/48479, which was published on September 30, 1999;

European Patent Application Publication No. EP 1 060 741, which was published on December 20, 2000;

U.S. Patent No. 4,145,410 to SEARS, which issued on March 20, 1979, together with patent family members reissue Patent Nos. RE 31,609 to SEARS,

which reissued on June 19, 1984 and RE 30,748 to SEARS, which reissued on September 22, 1981; and

U.S. Patent No. 5,422,120 to KIM, which issued on June 6, 1995, together with patent family member U.S. Patent No. 5,576,017 to KIM, which issued on November 19, 1996.

Further to 37 C.F.R. §1.98 (a)(2)(ii), copies of the U.S. patents and U.S. patent application publications are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Except for U.S. patents and U.S. patent application publications, Copies of the above-noted documents are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material. However, if an Office Action on the merits has issued and is crossing this statement in the mail, the undersigned hereby authorizes the Commissioner to charge any fee necessary for the consideration of this statement, including any payment under 37 C.F.R. §1.17 (p) to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
Hee-Yong LEE et al.



Stephen M. Roylance  
Bruce H. Bernstein  
Reg. No. 29,027  
Reg. No. 31,296

February 10, 2005  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191

FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P26228Application No.  
10/512, 090INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT  
(Use several sheets if necessary)Applicant  
Hee-Yong LEE et al.Filing Date  
May 9, 2003Group  
Not Yet Assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		4	8	1	8	5	4	2	04/04/89	Deluca ET AL.			
		5	9	4	2	2	5	3	08/24/89	GOMBOTZ et al.			
		5	8	0	4	5	5	7	09/08/98	CLELAND et al.			
		5	0	1	9	4	0	0	05/28/91	GOMBOTZ et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	01	/	2	8	5	2	4		04/26/01	W.I.P.O			
	99	/	4	8	4	7	9		09/30/99	W.I.P.O			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		1	J. HELLER et al., Biomaterials, Vol. 4, pp. 262-266, October 1983.
		2	R. LANGER, Science, Vol. 249, No. 4976, pp. 1527-1533, September 28, 1990.
		3	H. OKADA et al., Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 12, No. 1, pp. 1-99, 1995.
		4	T.G. PARK, Biomaterials, Vol. 16, pp. 1123-1130, 1995.
		5	J.M. ANDERSON, Advanced Drug Delivery Reviews, Vol. 28, pp. 5-24, 1997.
		6	M.A. TRACY et al., Biomaterials, Vol. 20, pp. 1057-1062, 1999.
		7	J.P. McGEE et al., Journal of Controlled Release, Vol. 34, pp. 77-86, 1995.
		8	B. GANDER et al., J. Microencapsulation, Vol. 12, No. 1, pp. 83-97, 1995.
		9	P.B. O'DONNELL et al., Advanced Drug Delivery Reviews, Vol. 28, pp. 25-42, 1997.
1	0	H.K. KIM et al., Biotechnol. Bioeng., Vol. 65, pp. 659-667, 1999.	
1	1	G. CROTTES et al., J. Microencapsulation, Vol. 15, No. 6, pp. 699-713.	
1	2	J.L. CLELAND et al., Pharmaceutical Research, Vol. 13, No. 10, pp. 1464-1475, 1996.	
1	3	J.L. CLELAND et al., Pharmaceutical Research, Vol. 14, No. 4, pp. 420-425, 1997.	
1	4	J.-M. PEAN et al., Pharmaceutical Research, Vol. 16, No. 8, pp. 1294-1299, 1999.	
1	5	A. SANCHEZ et al., International Journal of Pharmaceutics, Vol. 185, pp. 255-266, 1999.	
1	6	E.C. LAVELLE et al., Vaccine, Vol. 17, pp. 512-529, 1999.	
1	7	M. IWATA et al., J. Microencapsulation, Vol. 16, No. 1, pp. 49-58, 1999.	
1	8	J.L. CLELAND et al., Current Opinion in Biotechnology, Vol. 12, pp. 212-219, 2001.	
1	9	P.S. DANNIES, Molecular and Cellular Endocrinology, Vol. 177, pp. 87-93, 2001.	
2	0	M.G. FARQUHAR et al., Endocrinology, Vol. 102, No. 1, pp. 296-311, 1978.	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. P26228	Application No. 10/512, 090
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use several sheets if necessary)		Applicant Hee-Yong LEE et al.	
		Filing Date May 9, 2003	Group Not Yet Assigned

## **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5	6	5	4	0	1	0	08/05/97	JOUNSON et al.			
	2003	0	0	5	9	4	7	4	03/27/03	SCOTT et al.			
		6	4	5	8	3	8	7	10/01/02	SCOTT et al.			
		4	1	4	5	4	1	0	03/20/79	SEARS			
			3	1	6	0	9		06/19/84	SEARS			
		5	4	2	2	1	2	0	06/06/95	KIM			
		5	5	7	6	0	1	7	11/19/96	KIM			

## **FOREIGN PATENT DOCUMENTS**

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

EXAMINER

**DATE CONSIDERED**

**\*EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.